510(k) Summary
21 CFR 876.5010

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-638-2925
Fax:	480-449-2542
Contact:	Christoph Wagner von Hoff, Regulatory Affairs Specialist
Date:	March 21st , 2013

AUG 30 2013

2. Subject Device:

Device Trade Name:	LifeStent® / XL Biliary Stent System
Common or Usual Name:	Biliary Stent
Classification:	Class II
Classification Name:	Biliary, Catheter (FGE), Class II
Regulation Number:	21 CFR 876.5010

3. Predicate Device:

LifeStent FlexStar Biliary Stent System (K053404; cleared December 21st, 2005)
LifeStent FlexStar XL Biliary Stent System (K060487; cleared March 23rd, 2006)
E-LUMINEXX® Biliary Stent (K063532; cleared May 30th, 2008)

4. Device Description:

The LifeStent /XL Biliary Stent System consists of a self-expanding stent that is provided loaded into an over-the-wire catheter that acts as a delivery system. The stent is a permanently implanted device used to maintain patency of a major bile duct obstructed by tissue of an impinging tumor, The flexible, self-expanding

stent is made by laser cutting an open lattice design into a nitinol tube. The subject device is supplied in lengths of 20-120 mm and diameter of 5 mm. A delivery system comprised of a dilator (inner shaft) and a sheath to enhance trackability, which are linked together by means of a handle. The dilator terminates distally in an atraumatic catheter tip and originates proximally in a luer hub designed to accept a 0.035" guidewire. The self-expanding stent is constrained within the space between the dilator and the sheath. Deployment is initiated by rotating the thumbwheel in the direction of the handle arrow while holding the handle in a fixed position until complete deployment of the stent is achieved.

5. Indications for Use of Device:

The LifeStent® / XL Biliary Stent System is indicated for use in the palliation of malignant strictures (neoplasms) in the biliary tree.

6. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended use
- Indications for use
- Target population
- Fundamental scientific technology
- Operating principle
- Implant design and materials
- Packaging materials and configuration
- Sterility

The subject device is a modification of the predicate devices LifeStent FlexStar Biliary Stent System (K053404) and the LifeStent FlexStar XL Biliary Stent System (K060487). The subject device and the predicate devices are different in the following manner:

- The only change from the predicate devices is a 5 mm stent diameter for lengths 20-120 mm to the same indications for use as the predicate device.

7. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA guidance document, "Guidance for the content of premarket notifications for metal expandable Biliary Stents," dated February 5th, 1998, and internal risk assessment procedures, the following non-clinical tests were performed:

- Deployment Testing
- Expansion Force Testing
- Compression Force Testing
- Dimensional Testing
- Corrosion Testing

The results demonstrate that the technological characteristics and performance criteria of the 5mm LifeStent® / XL Biliary Stent System fulfill the same specifications as the predicate devices and therefore perform as safely and as effectively as the legally marketed predicate device.

8. Conclusion:

The LifeStent® / XL Biliary Stent System is substantially equivalent to the legally marketed predicate devices, the LifeStent FlexStar Biliary Stent System (K053404) and the LifeStent FlexStar XL Biliary Stent System (K060487).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

C.R. Bard, Inc
% Christoph Wagner von Hoff
Regulatory Affairs
Bard Peripheral Vascular
1415 West 3rd Street
Tempe, AZ 85281

Re: K130792
Trade/Device Name: LifeStent® Biliary Stent System
LifeStent® XL Biliary Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: August 1, 2013
Received: August 2, 2013

Dear Christoph Wagner von Hoff,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy L. Foreman -S

Christy L. Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130792

Device Name: LifeStent® / XL Biliary Stent System

Indications for Use: The LifeStent / XL Biliary Stent System is indicated for use in the palliation of malignant strictures (neoplasms) in the biliary tree.

Prescription Use ___X___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S